K010041

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3. 510(k) Summary of Safety and Effectiveness

In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

Description statements were relied on to ascertain the intended uses and technological features of legally marketed devices, and the substantial equivalence to the SLT Diffuser™ Fiber to such legally marketed devices. The comparison of the intended use and technological features of this device to other legally marketed devices indicates that this device is substantially equivalent to legally marketed predicate devices with regard to safety, effectiveness and intended use.

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Surgical Laser Technologies, Inc.
147 Keystone Drive
Montgomeryville, PA 18936

Phone: 215/619-3600
Contact Person: Davis Woodward
Date prepared: 11/20/00

Names of Device; Name/Address of Sponsor

Company Name; SLT Diffuser™ Fiber
Classification Name: Accessory to powered surgical laser instrument
Common Name: Diffusing laser fiber or probe

Surgical Laser Technologies, Inc.
147 Keystone Drive
Montgomeryville, PA 18936

Predicate Devices

Indigo Diffuser-Tip™ fiberoptic
Dornier ITT Light Guide
Rare Earth Lightstic®
SLT Interstitial Contact Laser™ Probes

Description of Device.

The SLT Diffuser™ fiber provides laser energy to tissue situated at its distal region. It is comprised of a diffusing tip assembly that is affixed to a standard fused silica fiberoptic cable. The fiberoptic is used with wavelengths from 940 nm to 1064 nm. The diffusing tip assembly is comprised of a plastic tube that is filled with a transparent matrix in which are embedded light-dispersing particles. The distal end of the tube is sealed off with a plastic end plug. A reflecting means is placed on the proximal surface of the end plug. The SLT Diffuser™ fiber emits laser energy substantially uniformly from the sidewalls of the tube and very little forward, through the end plug.. The device may be used with a cooling catheter.

Intended Use; Indications for Use

The intended use of this device, and its optional accouterments, is the same as the intended use of other diffusing laser probes and fibers marketed to provide the same tissue effects: viz. to necrotize or coagulate soft tissue through interstitial irradiation and/or thermal therapy, whether in open or closed surgery, whether used with handpieces or without, whether used with coolant or not, and whether used in contact or non-contact with tissue. The device is compatible with MRI, ultrasound and CT scanning imaging systems.

The SLT Diffuser™ Fiber is indicated for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy in medicine and surgery in cardiovascular thoracic surgery (excluding the heart and the vessels in the pericardial sac), dermatology, ear-nose-throat surgery, gastroenterology, general surgery, gynecology, head and neck surgery, neurosurgery, plastic surgery, pulmonology, radiology and urology, for wavelengths from 940 nm to 1064 nm.

Comparison to Predicate Devices

When the SLT Diffuser™ Fiber and the Indigo fiber (its primary predicate device) and the Rare Earth device, are compared, the following differences are seen: the Indigo device has a pointed distal tip, whereas the SLT device, like the Rare Earth device, has a blunted tip; in the Indigo device, the scattering particles are embedded in a tube that surrounds the fiberoptic, whereas in the SLT device, as in the Rare Earth device, the scattering particles are embedded in a matrix that lies fore of the fiberoptic; the Indigo device is for wavelengths from 800 nm to 850 nm, whereas the SLT device is for wavelengths from 940 nm to 1064 nm; the Indigo device has a temperature sensor but is typically not used with external coolant, whereas the SLT device has no sensor, like the Rare Earth device, but typically is used with a coolant. SLT believes that the foregoing differences are relatively minor and should not raise any concerns regarding the overall safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 7 2001

Surgical Laser Technologies, Inc.
c/o Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462

Re: K010041
Trade Name: SLT Diffuser™ Fiber
Somatex® Irrigated Power Laser Applicator Kit
Somatex® Laser Applicator Kit
Regulatory Class: II
Product Code: GEX
Dated: February 19, 2001
Received: February 20, 2001

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K010041

Device Name: Diffuser Fiber

Indications for Use:

The SLT Diffuser™ Fiber is indicated for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy in medicine and surgery in cardiovascular thoracic surgery (excluding the heart and the vessels in the pericardial sac), dermatology, ear-nose-throat surgery, gastroenterology, general surgery, gynecology, head and neck surgery, neurosurgery, plastic surgery, pulmonology, radiology and urology, for wavelengths from 940 nm to 1064 nm.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

Miriam C Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010041